K090843

510(k) SUMMARY

JUN 17 2009

Contact: Manfred Plaumann

Date prepared: March 25th, 2009

Trade or proprietary name: **Amaris® Gingiva**

Classification name: Material, Tooth Shade, Resin (872.3690)

Predicate device: Clearfil ST Opaquer/Kuraray Co. Ltd., K001913

Device description: Amaris® gingival shade is a light-curing radiopaque restorative which contains 80% fillers in a methacrylate matrix and which can be cured with blue light. Amaris® gingival shade is used to treat cervical defects and exposed, discoloured or hypersensitive necks of teeth, especially in the visible anterior area. The gingival-like shade and the Amaris® Gingiva Opaquer system allow the correct reproduction of the gingiva in its shade.

Intended use:

Amaris® Gingiva Opaquer is intended for use in conjunction with Amaris Gingiva for the following applications:

- for the aesthetic covering and masking of discoloured hypersensitive necks of teeth, especially in the visible anterior area.
- for corrections of the red-white aesthetics.
- for masking and lightening of crown and bridge restorations and margins.

Technological characteristics: All of the components of Amaris® Gingiva Opaquer are found in the legally marketed device Clearfil ST Opaquer/Kuraray Co. Ltd., K001913.

The prior use of all of the components of Amaris® Gingiva Opaquer in legally marketed devices supports our decision that additional testing for cytotoxicity and mutagenicity as well as additional biocompatibility studies with the final formulation are not necessary. We believe that the prior use of the components of Amaris® Gingiva Opaquer in legally marketed devices and the performance data and results provided support the safety and effectiveness of Amaris® Gingiva Opaquer for the intended use.

VOCO GmbH, March 25th, 2009

VOCO GMBH
Anton-Flettner-Str. 1-3
27472 CUXHAVEN
Germany

Manfred Plaumann
Managing Board

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2009

Dr. T. Gerkensmeier
Regulatory Affairs
VOCO GmbH
Anton-Flettner-Strasse 1-3
D-27472 Cuxhaven
GERMANY

Re: K090843
Trade/Device Name: Amaris® Gingiva Opaquer
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: June 3, 2009
Received: June 9, 2009

Dear Dr. Gerkensmeier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K090843

Device Name: **Amaris® Gingiva Opaquer**

Indications for Use:

Amaris® Gingiva Opaquer is intended for use in conjunction with Amaris Gingiva for the following applications:

- for the aesthetic covering and masking of discoloured hypersensitive necks of teeth, especially in the visible anterior area.
- for corrections of the red-white aesthetics.
- for masking and lightening of crown and bridge restorations and margins.

Prescription Use __X___ OR **Over-The-Counter Use** _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lori Murley for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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